

REMARKS

Reconsideration of the application is respectfully requested.

Claims 1-64 are in the application. Through this Amendment, claims 1, 16, 33, 49, 52, 53, 56, 59 and 62 have been amended.

In the Official Action, the Examiner rejected claims 1-3, 16-20, 33-36 and 49-52 under 35 U.S.C. §102(b) as being allegedly anticipated by Baldwin et al. (U.S. Patent No. 3,071,135).

Baldwin et al. is directed to a hollow needle. The needle includes a beveled front face 12 which includes beveled side faces 13. A heel surface 15 is also provided. (Col. 3, ll. 12-16). The heel surface 15 is “dished” to define a depression or recess 17, as clearly shown in Fig. 3. (Col. 3, ll. 41-50). There is no disclosure or suggestion in Baldwin et al. of what angles are to be used in forming the side faces 13, the heel 15, or the recess 17.

Claim 1 is directed to a needle having a multi-beveled point “comprised of a primary bevel, a pair of tip bevels, and a pair of middle bevels”. Further, the “planar angles of said primary bevel and said pair of middle bevels are substantial equal.” As indicated above, there is no disclosure or suggestion in Baldwin et al. of what angles are to be used in forming the side faces 13, the heel 15, or the recess 17. As such, there is no disclosure or suggestion of having the planar angle of at least three different bevels be substantially equal (i.e., planar angle of the primary bevel and the planar angle of the pair of middle bevels). With reference to MPEP

§2125, the figures of Baldwin et al. can not be relied upon for disclosure of the angles. ("When the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.").

It must be noted that the specific claimed beveled configuration has been found by Applicants to provide a needle that requires less penetration force which, thus, causes less pain to be experienced by a patient. (See, paras. [0010]-[0012] of Applicants' specification). The claimed beveled structure provides a very beneficial and tangible result over the prior art, and it is not the result of optimization or other obvious determinations. It is respectfully submitted that claim 1, along with dependent claims 2-3, are patentable over Baldwin et al.

Claim 16 is directed to a needle having a multi-beveled point which includes "five bevels". The bevels are arranged such that "one of said plurality of bevels is provided on said cannula at a first planar angle, a first pair of said plurality of bevels are provided on said cannula at a second planar angle, and a second pair of said plurality of bevels are provided on said cannula at a third planar angle, wherein said first and second planar angles are substantially equal." As such, similar to claim 1, claim 16 requires that three bevels be provided at substantially equal planar angles. There is no disclosure or suggestion in Baldwin et al. of planar angles, much less having three bevels be at the same planar angle. It is respectfully submitted that claim 16, along with dependent claims 17-20, are patentable over Baldwin et al.

Claim 33 is directed to a needle having a multi-beveled point with "five bevels" wherein "each of said five bevels is provided on said cannula at an angle of rotation about said central axis". Claim 33 further states that "a first planar angle is defined at said bevel corresponding to a first rotational angle, a second planar angle is defined at said bevel corresponding to a second rotational angle, said first and second rotational angles being different with said first and second planar angles being substantially equal." Baldwin et al. does not provide such an arrangement. Both portions of the heel 15 are located at the same rotational angle relative to the central axis, while both side faces 13 are also located at the same rotational angle relative to the central axis. As discussed above, there is no disclosure in Baldwin et al. of planar angles. Even taking that both of the side faces 13 may be formed with the same planar angle or that both of the heel portions 15 about the recess 17 may be formed with the same planar angle, both side faces 13 and both heel portions 15 are at the same, not different, rotational angles relative to each other; there is no disclosure or suggestion in Baldwin et al. to have bevels at two different rotational-angle locations with the same planar angle. In other words, there is no disclosure or suggestion to have two or more of a side face 13, a heel portion 15, and/or recess 17 at the same planar angle. It is respectfully submitted that claim 33, along with dependent claims 34-36, are patentable over Baldwin et al.

Claim 49 is directed to a needle having a multi-beveled point with "first, second, third, fourth and fifth planar bevels". In contrast, Baldwin et al. does not provide at least five planar bevels in its device. As clearly shown in Fig. 3, the recess 17 is dished and not formed planar. Also, the shape of the heel 15 about the recess 17 is unclear, as well as, of the shape of the bevel

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side faces 13. In any regard, at least five planar surfaces are not shown or disclosed in Baldwin et al. Moreover, there is no suggestion or motivation to modify Baldwin et al., since the recess 17 must be dished. (See, col. 3, ll. 41-50). It is respectfully submitted that claim 49, along with dependent claims 50-51, are patentable over Baldwin et al.

Claim 52 is directed to a needle having a multi-beveled point "with a plurality of discrete planar bevels contiguously bounding said opening". As discussed above with respect to claim 49, Baldwin et al. fails to disclose or suggest such an arrangement. It is respectfully submitted that claim 52 is patentable over Baldwin et al.

The Examiner rejected claims 1-3, 16-20, 33-36 and 49-52 under 35 U.S.C. §102(b) as being allegedly anticipated by Ferguson (U.S. Patent No. 2,560,162).

Ferguson is directed to a needle structure which includes a bore 13 bounded by ground surfaces 12 and depression 15. Bevels 11 are also provided on the needle, but these bevels do not contiguously contact the bore 13.

Claims 1, 16, 33, 49, and 52 have all been amended to indicate that the bevels of the multi-beveled needle contiguously bound the opening or lumen of the needle. Claims 1, 16, 33 and 49 all require at least five bevels to be provided. This arrangement is not disclosed or suggested in Ferguson — i.e., Ferguson does not disclose or suggest at least five bevels contiguously bounding an opening or lumen of a needle. Further, claim 52 requires a bevel

located furthest from the tip to have the shortest length. Relative dimensions of the bevels are not disclosed in Ferguson. It is respectfully submitted that claims 1, 16, 33, 49 and 52, along with dependent claims 2-3, 17-20, 34-36 and 50-51, are patentable over Ferguson.

The Examiner rejected claims 1-52 under 35 U.S.C. §103(a) as being allegedly unpatentable over Baldwin et al. or Ferguson. The Examiner admitted that “Baldwin or Ferguson fail to explicitly disclose the specific rotational angle or planar angle of each embodiment.” The Examiner asserted that “it would have been obvious for one of ordinary skill in the art to modify either Baldwin or Ferguson to have the specific angle being chosen for either the planar angle or the rotational angle because of routine experimentation.” The Examiner also stated that “there is no specific criticality or unexpected result being derived from the angles chosen”.

As indicated above, the claimed multi-beveled needle had been found to provide real and tangible results, which are inventive and not the result of optimization. Reference is made to para. [0049] of Applicants’ specification and the table that follows thereafter which show that much lower penetration forces are required with a needle formed in accordance with the subject invention than with a prior art needle (in the table specified as having a penetration force of 468.5 gm.f). It is respectfully submitted that, contrary to the Examiner’s assertions, the claimed dimensions are critical and achieve superior results. It is respectfully submitted that claims 1-52 are patentable over Baldwin et al. and Ferguson.

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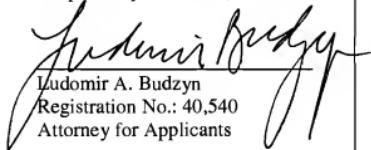
The Examiner rejected claims 53-64 under 35 U.S.C. §103(a) as being allegedly unpatentable over Baldwin et al. or Ferguson, in view of Burns (U.S. Patent No. 5,643,219). The Examiner admitted that “Baldwin et al. or Ferguson teach the claimed invention but fail to disclose a needle shield for the needle and attaching the needle to a syringe.” The Examiner relied on Burns for allegedly overcoming this deficiency.

Claim 53 includes similar limitations to claim 1; claim 56 includes similar limitations to claim 33; claim 59 includes similar limitations to claim 49; and, claim 62 includes similar limitations to claim 52. For the reasons set forth above, these claims are distinguishable over Baldwin et al. In addition, these claims include the limitation that the bevels contiguously bound the opening or lumen. As such, these claims are also distinguishable from Ferguson. Burns was merely cited for disclosing a needle cap and does not overcome the deficiencies noted above of Baldwin et al. and Ferguson. It is respectfully submitted that claims 53-64 are patentable over Baldwin et al., Ferguson and Burns, each taken alone or in combination.

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Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,


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